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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,511	11/14/2003	William W. Alston	0175.00	9835

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NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
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EXAMINER

MITCHELL, TEENA KAY

ART UNIT PAPER NUMBER

3743

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,511

Applicant(s)ALSTON ET AL. **Examiner**

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to because some of the reference numerals are not legible especially in Figs. 4A-4E. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are

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not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Page 7, line 27, "...non-circular cross section 270..." should be amended to read --non-circular cross section 170--.

Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 15-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Valentini et.al. (4,069,819).

With respect to claim 1, Valentini discloses a body defining a chamber ((B) having an air inlet (H) and an outlet (A), wherein the chamber is sized to receive a receptacle (C) containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber (Figs. 5, 6); wherein the chamber comprises a longitudinal axis which is substantially parallel to an inhalation direction and wherein the chamber has a cross-section orthogonal to its longitudinal axis that is non-circular (Col.

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1, lines 27-35; based on the disclosure of elements of inclined surfaces, helicoidal parts or the like it is inherent that the chamber could have a cross-section orthogonal to its longitudinal axis that is non-circular, whereby when a user inhales, air enters into the chamber through the inlet (H) to cause the receptacle to move within the chamber so that the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet.

With respect to claim 2, Valentini discloses wherein the receptacle (C) is a capsule.

With respect to claim 3, Valentini discloses wherein the longitudinal axis of the chamber and the longitudinal axis of the capsule form an angle of less than about 45 degrees during use (Figs. 5, 6).

With respect to claim 4, Valentini discloses wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (Fig. 5).

With respect to claim 5, Valentini discloses wherein the width of the chamber is less than the length of the capsule (Fig. 5).

With respect to claim 6, Valentini discloses a puncturing member (D) moveable within the chamber to create the opening in the receptacle.

With respect to claim 7, Valentini discloses wherein the puncture member comprises a sharpened tip for penetrating the wall of the receptacle (Figs. 3, 5).

With respect to claim 8, Valentini discloses wherein the puncture member comprises a pair of sharpened tips for penetrating the wall of the receptacle (Figs. 3, 5).

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With respect to claim 9, Valentini discloses wherein the puncture member is positioned to pierce only one end of the receptacle (Figs. 3, 5).

With respect to claim 15 note rejection of claim 1 above.

With respect to claim 16, Valentini discloses wherein the receptacle is a capsule (Figs. 3, 5, 6).

With respect to claim 17, Valentini discloses wherein the longitudinal axis of the chamber and the longitudinal axis of the capsule form an angle of less than about 45° during use (Figs. 3, 5).

With respect to claim 18, Valentini discloses wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (Figs. 3, 5).

With respect to claim 19, Valentini discloses wherein the width of the chamber is less than the length of the capsule (Figs. 3, 5).

With respect to claim 20, Valentini discloses a puncturing member (D) moveable within the chamber to create the opening in the receptacle (Figs. 3, 5).

With respect to claim 21, Valentini discloses wherein the inlet is shaped to create a swirling airflow with the chamber (Figs. 5, 6).

With respect to claims 22-25, note rejections of claims 1, 16, 20, and 21 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-14 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini (4,069,819).

Valentini does not disclose the non-circular cross-section comprising one or more projections that extend into the chamber. Applicant has not disclosed that having one or more projections is better than any other means for deagglomeration of particles in

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an inhaler device. Accordingly, the use of one or more projections is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Valentini.

With respect to claims 12-14, note rejection of claim 11 above.

With respect to claims 26-28 the method steps would have been obvious because they would have resulted from the use of the device of Valentini.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show aerosolization devices: 6,715,486; 6,418,926; 6,230,707; 5,379,763; 4,889,114; 4,265,236; 3,809,084.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell
Examiner
Art Unit 3743
February 5, 2005